K121989

Exactech® Optecure® and Optecure® + CCC
Traditional 510(k)

510(k) Summary

NOV 27 2012

Company: Exactech®, Inc
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Gainesville, FL 32653

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Date of Submission: September 25, 2012

Contact Person: Gina Cassidy
Director, Regulatory Affairs

Proprietary Name: Exactech® Optecure® and Optecure® + CCC

Common Name: Bone Void Filler

Classification Name: 21CFR §888.3045 Resorbable calcium salt bone

Regulatory Class: II

Product Code: MQV, MBP

Classification Panel: Orthopedic

Legally Marketed Devices for Substantial Equivalence Comparison:

Produc Code	Manufacturer	510(k) Number	Product
MQV, MBP	Exactech Inc.	K050806	Optecure
MQV, MBP	Exactech, Inc.	K061668	Optecure+CCC
MQV, MBP	Musculoskeletal Transplant Founation	K110003 K113167	MTF New Bone Void Filler
MQV, MBP	Musculoskeletal Transplant Founation	K053218 K063676 K080399 K103784 K103795	DBX Demineralized Bone Matrix Putty

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Device Description/Purpose of Premarket Notification

Optecure and Optecure + CCC are aseptically processed, single use, ready-to-mix devices intended for use as bone graft extenders (extremities, spine and pelvis) and as bone void fillers (extremities and pelvis) for bony voids or gaps of the skeletal system that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.

Optecure products are provided in the form of a kit with pre-measured polymer powder, demineralized bone matrix (DBM), corticocancellous bone chips (CCC), pre-measured mixing solution and all the tools necessary to mix the components. After the powder is hydrated, the resultant putty can then be handled and placed in the appropriate bone voids or gaps.

Optecure products gradually resorb and are replaced with new bone during the healing process.

The purpose of this 510(k) submission is to expand the current Indications for Use so that Optecure and Optecure + CCC may be used in combination with autogenous bone marrow as a bone graft extender.

Indications for Use

Optecure and Optecure +CCC are intended for use in combination with autogenous bone as a bone graft extender (extremities, spine and pelvis) and as bone void fillers (extremities and pelvis) for bony voids or gaps of the skeletal system that are not intrinsic to the stability of the bony structure. Optecure and Optecure + CCC can be used with autogenous bone marrow. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.

Optecure and Optecure +CCC may be used with rigid fixation systems.

Osteoinductive Potential

Samples from each lot of donor demineralized bone matrix (DBM) are formulated with the carrier and tested for osteoinductivity in an *in vivo* athymic mouse assay.

Osteoinduction assay results using the athymic mouse assay should not be interpreted to predict clinical performance in human subjects.

Preclinical testing

Optecure and Optecure + CCC formulations underwent several preclinical testing including, but not limited to, testing on the handling properties, osteoinductive potential, and bone healing effectiveness of the formulations in both tibial defect and spinal fusion animal models. The results of these studies are substantially equivalent to those of the predicate devices identified in this 510(k) Summary.

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Substantial Equivalence Conclusion

Optecure® and Optecure® + CCC are substantially equivalent to the legally marketed predicate devices identified above in that they share either same or similar intended use, design, material composition and functions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

November 27, 2012

Exactech, Incorporated
Ms. Gina Cassidy
Director, Regulatory Affairs
2320 Northwest 66th Court
Gainesville, Florida 32653

Re: K121989
Trade/Device Name: Exactech® Optecure® and Optecure® + CCC
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV, MBP
Dated: September 25, 2012
Received: September 26, 2012

Dear Ms. Cassidy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exactech® Optecure® and Optecure® + CCC
Traditional 510(k)

Indications for Use Statement

510(k) Number: K121989

Device Name: Exactech® Optecure® and Optecure® + CCC

INDICATIONS FOR USE:
Optecure and Optecure +CCC are intended for use in combination with autogenous bone as a bone graft extender (extremities, spine and pelvis) and as bone void fillers (extremities and pelvis) for bony voids or gaps of the skeletal system that are not intrinsic to the stability of the bony structure. Optecure and Optecure + CCC can be used with autogenous bone marrow. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.

Optecure and Optecure +CCC may be used with rigid fixation systems.

Prescription Use __X__ **and/or** **Over-The-Counter Use _____**
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

Please do not write below this line – use another page if needed.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number K121989